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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/606,779	06/28/00	GRIFFIN J	SCRIP1180-3

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EXAMINER	
SAUNDERS,D	
ART UNIT	PAPER NUMBER
1644	7

DATE MAILED: 09/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/606,779	Applicant(s) GRIFFIN ET AL.	
	Examiner David A Saunders	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Claim 1 is pending and under examination.

The disclosure is objected to because of the following informalities:

> Page 1, lines 5-6 contains information that partly duplicates what was entered by preliminary amendment at line 1.

Appropriate correction is required.

> A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 1 is rejected under 35 USC 101 as claiming the same invention as claim 1 of prior US patent 5,834,223. This is a double patenting rejection.

You are hereby notified under 37 CFR 1.607(d) that an applicant is seeking to provoke an interference with you US Patent 5,834,223, which contains a claim identical to instant claim 1.

The identity of the applicant will not be disclosed unless an interference is declared.

If a final decision is made not to declare an interference, a notice to that effect will be placed in the patent file and will be sent to the patentee.

If an interference is declared, notice thereof will be made under 37 CFR 1.611.

Since instant claim 1 is not in condition for allowance, no interference can be declared that includeds the instant application.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dahlback (WO 94/17415).

Dahlback discloses (page 15) coagulation assays of plasma samples wherein the samples are diluted in excess plasma that is deficient in the entity to be assayed. Dahlback discloses assays (page 21) for APC cofactor 2 activity which employ added APTT (a procoagulant), a plasma (from a patient showing a poor APC response, i.e. APC resistance), APC and calcium. It would have been obvious to add the taught diluent and components to any plasma sample for which one desired to assay for APC resistance. Further, since Dalhback teaches that APC cofactor 2 activity is due to the same protein that has Factor V activity (entire disclosure), it would have been obvious and more convenient to use any known and available Factor-V deficient plasma in lieu of the particular AS plasma (deficient in APC cofactor 2 activity) used by Dahlback. Dahlback further teaches that the presence of APC cofactor 2 activity results in an increase in clotting time (page 21). One would have thus expected that a sample from a patient showing APC resistance (i.e. poor APC cofactor 2 activity) would show a decrease in clotting time, as required by instant claim 1, part b), i). Comparison to a control sample having normal coagulation/anticoagulation factors was art conventional in order to standardize the readings. Hence the instantly recited comparing would have been obvious.

i.e. clotting is delayed as taught in 6,114,136 & Cat.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dahlback et al (PNAS, 91, 1396, 1994).

Dahlback et al teach (page 1397) a clotting assay for APC cofactor 2 activity that involves the same diluent and added reagents as that noted supra in the Dalhback WO publication. For like reasons stated with respect to the WO reference, the features of claim 1 would have been obvious

On attached form 1449, non-initialed references are not available to the examiner, since related applications are presently unavailable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A Saunders whose telephone number is 703-308-3976. The examiner can normally be reached on M-F from 8:15 to 4:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

David A Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1644

Typed 9/12/01 DAS

John J. Doll

John J. Doll, Director
Technology Center 1600